UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	NO. 4:17-CR-00403
	)	
v.	)	
	)	(JUDGE BRANN)
	)	
RAYMOND KRAYNAK,	)	
Defendant	)	(ELECTRONICALLY FILED)

GOVERNMENT'S BRIEF IN OPPOSITION TO KRAYNAK'S SUPPLEMENTAL BRIEF IN SUPPORT OF HIS MOTION *IN LIMINE*

The United States hereby opposes defendant Raymond Kraynak's supplemental brief in support of his motion *in limine* to preclude evidence under Federal Rule of Evidence 402, 403, and 404. Doc. 134. In support of its opposition the United States submits the following grounds.

I. FACTUAL BACKGROUND

A. Overview

Raymond Kraynak was a Doctor of Osteopathy (D.O.) who practiced medicine at the Keystone Family Medicine Associates P.C., 28 East 5th Street, Mount Carmel, Pennsylvania, and at 235 West Spruce Street, Shamokin, Pennsylvania. The defendant was licensed by the Commonwealth of Pennsylvania to practice medicine and registered by

the Drug Enforcement Administration (DEA) to prescribe Schedule II, III, IV and V controlled substances. As an osteopathic doctor, Kraynak was authorized to prescribe and/or dispense Schedule II controlled substances to patients and to prescribe medicine to patients, including controlled substances, for legitimate medical purposes and in the usual course of professional practice. The indictment alleges that many of the prescriptions issued by Kraynak were not issued for a legitimate medical purpose and were not issued within the usual course of a professional medical practice.

The 19-count indictment returned December 20, 2017 charges Kraynak with violations of 21 U.S.C. § 841(a) (1) for the distribution and dispensing of controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. (Doc. 3) Counts 1 through 12 concern twelve individual patients. Counts 13 through 17 address five of those twelve patients, and it is alleged in those counts that the defendant's distribution and dispensing of a controlled substance resulted in the deaths of those five patients. Counts 18 and 19 charge violations of 21 U.S.C. § 856(a)(1), for the defendant's maintaining locations at 28 East 5th Street, Mount Carmel,

Pennsylvania, and at 235 West Spruce Street, Shamokin, Pennsylvania for the purpose of unlawfully distributing controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.

A review of the defendant's medical records for the time frame of this indictment, obtained by search warrants during the course of this extensive DEA investigation, show that the records were routinely incomplete or missing and that the medical records failed to contain the required information regarding symptoms observed and reported, diagnosis of condition, direction for use, changes in symptoms observed and reported in their diagnosis of the condition for which the controlled substance was being given and in the directions given to the patient.

B. Administrative Licensing and Medical Board Actions

On April 11, 2012, the Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs (BPOA) entered into a Consent Agreement and Order with Kraynak to resolve a show cause order regarding the following allegations:

- During the period of January 2007 through June 2008, Kraynak prescribed large quantities of various controlled substances to seven separate patients.

- Kraynak failed to perform a physical examination of several of the patients pursuant to the prescription of controlled substances to these patients.
- Kraynak failed to document justification in the medical record for many of the controlled substances that he prescribed for the patients.
- Patients consistently requested new prescriptions for controlled substances prior to the end of their current prescriptions.
- Kraynak prescribed increasing doses of controlled substances to the patients.
- Kraynak did not document pill counts for patients.
- Kraynak did not document a narcotic agreement with patients.
- Kraynak did not document whether urine drug screening was provided to patients.

While admitting no wrongdoing, Kraynak consented to the order issued and agreed with the following:

- Kraynak departed from, or failed to conform to, standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician to patients.
- Kraynak agreed to attend and complete the "Intensive Course in Controlled Substance Management" at Case Western Reserve University School of Medicine, which consists of thirty-one hours.
- Kraynak shall institute, within ninety days of the adoption of the Consent Agreement, contracts for the management of patients with complaints of chronic pain and enforce the terms which shall include that all controlled substances be filled at one pharmacy, that all controlled substances be prescribed by Kraynak, and that unannounced urine or serum toxicology screens may be requested.

- Kraynak agrees to engage a professional office management company to review the documentation practices instituted by him for chronic pain patients.
- Kraynak was also ordered to pay a Civil Penalty of $2500.00.

GEX 1, 8-9.[1]

On October 28, 2013, the BPOA filed another order to show cause alleging that Kraynak violated the Osteopathic Medical Practice Act by departing from, or failing to conform to standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician for three patients. The order to show cause also alleged that Kraynak violated the Osteopath Board regulations by failing to annotate pertinent clinical information in medical records for the patients. GEX 1, 9.

In July 2014, the Pennsylvania State Board of Osteopathic Medicine conducted a hearing on the order to show cause regarding the OTSC. On January 19, 2016, the hearing examiner, in a proposed order, found that Kraynak was not subject to disciplinary action for departing from, or failing to conform to standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of

[1] GEX 1, 2, and 3 refer to the sealed exhibits filed with the Government's initial brief in opposition to Kraynak's motion *in limine*.

controlled substances by a family physician, but did find that Kraynak was subject to disciplinary action for violating Board regulations by failing to annotate pertinent clinical information in medical records. Kraynak was ordered to complete six hours of remedial continuing medical education related to patient medical record documentation, in addition to any standard continuing medical educational requirements imposed by Board regulations. GEX 1, 10-11.

C. PMP and Pharmacy Records

1. PMP Records

During the investigation of Kraynak's prescription practices, DEA investigators reviewed prescription monitoring reports (PMP) based on data collected by the Pennsylvania Prescription Drug Monitoring Program (PDMP), which contain prescription data for all Schedule II controlled substances dispensed by pharmacies in the Commonwealth of Pennsylvania. GEX 1, 21. All states and the District of Columbia currently utilize some form of electronic prescription drug monitoring database in which data from all prescriptions for controlled substances filled by pharmacies within the state are recorded. Data from these state databases is routinely admitted as evidence in federal court when

an individual is charged with prescribing or dispensing controlled substances outside the usual course of professional practice.[2]

Pharmacies are required by law in Pennsylvania to report the patient's name, the particular Schedule II controlled substance and dosage dispensed, quantity dispensed, number of days supplied, prescribing physician's name, DEA registration number, and the dispensing pharmacy's name and DEA registration number, as well as the date the prescription was written, the date it was dispensed, and information about the recipient. *See* Pennsylvania P.L. 2911, Act 191.

PMP reports reviewed by DEA investigators showed that – despite

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[2] A survey of cases across the nation in which PDMP data was admitted, typically without objection, yielded the following non-exhaustive list: *United States v. Mirilishvili*, 2016 U.S. Dist. LEXIS 21268, *14–17 (SDNY 2016) (admitting New York PDMP records) ; *United States v. Lowe*, 14-cr-0055-LGS (SDNY) (admitting New York PDMP records); *United States v. Wiseberg*, 13-cr-00794-AT (SDNY) (admitting New Jersey PDMP records); *United States v. Boccone*, 11-cr-00592 (EDVA) (admitting Virginia PDMP records); *United States v. Kabov*, 15-cr-00511-DMG (CDCA) (admitting California PDMP records); *United States v. Garg*, 15-cr-0007-JAK (CDCA) (admitting California PDMP records); *United States v. Sun*, 14-cr-00157 (CDCA) (admitting California PDMP records); *United States v. Bamdad*, 08-cr-00506-GW (CDCA) (admitting California PDMP records); *United States v. Mikaelian*, 11-cr-00922-DDP (CDCA) (admitting California PDMP records); *United States v. Gabriel-Diaz*, 12-cr-00011-CJC (CDCA) (admitting California PDMP records).

two prior show cause orders issued by the BPOA, a consent agreement, two remedial medical education courses on controlled substance management and patient medical record documentation, and review of his patient files by an outside consultant – Kraynak continued to prescribe excessive amounts of Schedule II controlled substances. Review of PMP reports by DEA investigators disclosed that from May of 2012 until the end of January 2016, Kraynak prescribed 3,622,598 Oxycodone pills. That total number represented 80.62% of all the controlled substances prescribed by him during that period. Furthermore, from January 1, 2016 through July 31, 2017, Kraynak prescribed an aggregate of 2,792,490 dosage units of oxycodone, hydrocodone, OxyContin and fentanyl to approximately 2,838 patients. This prescription volume made Kraynak the top prescriber for all of the Commonwealth of Pennsylvania for these controlled substances during that 19-month period.

2. Pharmacy Records

In addition to the PMP reports reviewed and analyzed by DEA, the United States intends to introduce records and summaries of records for the local pharmacies that filled his patients' prescriptions,

including prescription records for Kraynak's patients maintained by Walmart, RiteAid, CVS, Medicine Shoppe, Belski Community Pharmacy, and Burch's Pharmacy, among others. These pharmacies reported to DEA investigators similar high-volume prescription totals for Schedule II controlled substances and advised that they often refused to fill prescriptions for his patients because of abnormal volume and frequency of prescriptions and requests for early prescription refills. GEX 1, 19-20.

In reviewing PMP records of Kraynak's prescription activity, DEA investigators identified pharmacies where significant amounts of prescriptions for Schedule II controlled substances were filled for his patients, including Rite Aid, CVS and the Belski Pharmacy, among others, during the period from January 1, 2014 through November 11, 2015. GEX 1, 20. The investigators compared the total dosage units (DU's) dispensed by the pharmacies to the amount prescribed by Kraynak and determined that he was the pharmacies' highest prescriber of Schedule II controlled substances, and, furthermore, that the volume of his prescriptions significantly exceeded the second highest prescribers:

Pharmacy	Total DUs Dispensed by Pharmacy	Amount of DUs Prescribed by Dr. Kraynak	% of DUs Prescribed by Dr. Kraynak	Amount of DUs Prescribed by 2nd Highest Doctor	% of DUs Prescribed by 2nd Highest Doctor
Belski	1,073,000	580,000	54%	124,000	11.5%
Rite Aid #2478	1,135,000	485,000	42.7%	40,000	3.5%
Rite Aid #205	624,000	234,000	37.5%	33,000	5.3%
CVS	773,000	196,000	25%	65,000	8.4%

GEX 1, 20-21.

DEA investigators also learned from pharmacy staff that Kraynak's patients frequently tried to obtain early refills of Schedule II controlled substances, that prescriptions were issued days apart by Kraynak, and that pharmacies regularly refused to fill prescriptions written for Kraynak's patients. GEX 1, 20.

D. Referrals from Medical Insurers

Independent of PMP and pharmacy records showing his demonstrated pattern of prescribing unusually large volumes of Schedule II controlled substances, medical insurers, specifically Anthem Blue Cross Blue Shield ("Anthem") and the Medicare and Medicaid

programs, in reviewing prescription claims, identified excessive quantities and combinations of controlled substances prescribed by Kraynak and referred their findings to the BPOA and the DEA Resident Office in Scranton.

1. Anthem Referral to the Board of Osteopathic Medicine

On April 5, 2015, Anthem Blue Cross Blue Shield ("Anthem") referred Kraynak to the Pennsylvania Board of Osteopathic Medicine based on concerns of inappropriate prescribing of controlled substances and prescribing dangerous combinations of medications. GEX 3. Anthem included with its referral letter a copy of an investigative report prepared by its pharmacy benefits manager, Express Scripts, concerning prescription drug claims for Kraynak's patients. GEX 3, 3.

The Express Scripts report summarized findings for a claims review period between January 2012 and November 2014. GEX 3, 1. During that almost three-year period, Express Scripts determined that Kraynak prescribed 54,820 medications, 39% of which were controlled substances, and of the top ten medications prescribed by him, 80% were for narcotics. GEX 3, 1; 4. Express Scripts reported that Kraynak's prescribing habits differed considerably from other family practitioners

in Pennsylvania -- his top ten prescriptions included five types of oxycodone and hydrocodone that are among the Schedule II controlled substances charged in the Indictment, but those substances were not even listed in the top 10 medications prescribed by other Pennsylvania family medicine physicians like Kraynak. GEX 3, 1; 7.

2. Health Integrity LLC Referral

On June 3, 2015, the DEA Scranton RO received a referral regarding Kraynak from Health Integrity LLC, a Medicare Drug Integrity Contractor for the Centers for Medicare & Medicaid Services. Health Integrity was contracted to perform program safeguard functions to detect, deter and prevent fraud, waste and abuse related to the Medicare Part D Program, which provides funding to insurance plans to pay for the covered prescription drugs of Medicare beneficiaries. Health Integrity reviewed pharmacy claims for the period between January 1, 2013 to December 31, 2013 and identified Kraynak in the "Pill Mill Doctors Proactive Analysis Model" used to analyze claims for irregularities. According to the Health Integrity review of claims for medications prescribed by him, Kraynak had a predicted risk score of 977 on a scale of 1-1000. Based on its review,

Health Integrity suspected Kraynak of overprescribing controlled medication and not prescribing in a legitimate course of practice.

E. Combinations of Controlled Substances Prescribed by Kraynak

In addition to the dramatically higher amounts of oxycodone and hydrocodone prescribed by Kraynak as compared to other family physicians in Pennsylvania, the Anthem referral and Express Scripts report identified dangerous combinations of controlled substances prescribed by Kraynak. Although oxycodone and hydrocodone comprised most of the Kraynak patient claims summarized by Express Scripts, the report also identified a less frequently prescribed, but potentially dangerous combination of medications that include benzodiazepine (alprazolam), a muscle relaxer, carisoprodol, and an opioid-based pain medication, oxycodone or hydrocodone. GEX 3, 1; 7-8. According to the Express Scripts report, these combinations of medications have been identified as enhancing the effects of the drugs and creating a "high" that increases the potential for abuse by patients. GEX 3, 7-8.

Dr. Stephen Thomas's review of patient files and police, toxicology, and autopsy reports for RC, AK, ML, TM, CS, JL, and RW disclosed

that, both during and after the claims period reviewed by Express Scripts, Kraynak prescribed those patients combinations of oxycodone, hydrocodone, and benzodiazepine (Alprazolam/Xanax, Diazepam/Valium), and carisoprodol (Soma). According to Counts 13 through 17 of the Indictment, charging distribution and dispensing of controlled substances resulting in death, Kraynak prescribed patients RC, DH, AK, MI, and CS combinations of multiple controlled substances, including Alprazolam, Hydrocodone, Carisoprodol, Temazepam, Oxycodone, Diazepam, and Zolpidem. Doc. 3, 18-19. Based on patient medical records, pharmacy and prescription data, witness testimony, laboratory, toxicology, police and autopsy reports, and other information set forth in his report, Dr. Thomas opined that these combinations of controlled substances prescribed by Kraynak resulted in the death of the patients and were outside the usual course of professional practice and not for legitimate medical purpose.

II. ARGUMENT

A. Introduction

In his initial *in limine* motion Kraynak sought to exclude relevant PDMP (or PMP) information concerning the substantial amount of

prescriptions he issued for Schedule II controlled substances during the period charged in the indictment, any evidence about the dangerous combinations of controlled substances prescribed by him, and a report sent by an insurer, Anthem Blue Cross Blue Shield ("Anthem") to the Pennsylvania Board of Osteopathic Medicine concerning the high volume of Schedule II controlled substances prescribed to patients insured by Anthem. Doc. 119, 3. In his supplemental brief, he now expands the scope of his *in limine* request to exclude "1) any evidence of uncharged patients, 2) any evidence from the PDMP, 3) any Pennsylvania and Medical Board Actions and 4) Insurance Company Complaints under F.R.E. 401, 403, and 404." Doc. 134, 1. And, in his recently filed reply brief to the government's initial opposition to his *in limine* request, Kraynak offers additional grounds in support of his claim that the disputed evidence is prejudicial. Doc. 138.

When read most favorably to him, Kraynak essentially seeks to exclude all evidence concerning prescriptions and treatment for patients, not charged in the indictment, whom he treated, including the prescription activity reflected in PDMP reporting, pharmacy records, patient files, and insurance claims review and reporting, as well as

combinations of the substances he prescribed – stated simply, Kraynak's practice-wide prescription activity. The second category of evidence that he seeks to exclude are the two actions filed by state professional licensing authorities, which resulted in the requirement that he attend professional education courses concerning the prescription of controlled substances and the management of patient records and that he engage an outside consultant concerning the management of patient files.

In his supplemental and reply briefs, Kraynak contends that these two categories of evidence, practice-wide prescription records and the professional licensing actions, are neither proof of the elements of the offenses, nor of any other purpose under Federal Rule of Evidence 404(b), and further that the evidence is unduly prejudicial to him. But, as presented below, the disputed evidence directly demonstrates Kraynak's knowing and intentional distribution of Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose, in violation of 21 U.S.C. § 841(a)(1), not just as to specific patients but across his entire medical practice. Moreover, the evidence is direct proof of the elements of

Counts 18 and 19 charging Kraynak with maintaining two-drug involved medical offices in Shamokin and Mount Carmel from January 2006 through November 2017.

Alternatively, the contested evidence is admissible under Federal of Evidence 404(b) to prove a plan, design and scheme to prescribe controlled substances for other than legitimate medical purposes and not in the usual course of professional practice, Kraynak's knowledge and understanding of legitimate medical purposes and the usual course of professional practice, his intent to prescribe excessive amounts of controlled substances despite knowledge of those professional standards and requirements, and the absence of mistake, accident, or other innocent reason in prescribing excessive and inappropriate quantities and combinations of controlled substances.[3]

A. The evidence is direct proof of the elements of the offenses.

1. The applicable legal standard

[3] In this opposition brief, the United States will focus on the additional arguments raised by Kraynak in his supplemental and reply *in limine* briefs, Doc. 134; 138, and incorporates herein the grounds presented in its initial brief opposing Kraynak's motion *in limine*. Doc. 131. To avoid unnecessary repetition and duplication, the United States occasionally will cross-reference the arguments and authorities submitted in its initial brief in opposition.

Federal Rule of Evidence 404(b) " 'does not extend to evidence of acts which are 'intrinsic' to the charged offense.' " *United States v. Cross*, 308 F.3d 308, 320 (3d Cir. 2002) (citing Fed.R.Evid. 404(b) advisory committee's note). "Intrinsic evidence need not be analyzed under Rule 404(b) because it is not '[e]vidence of any crime, wrong, or other act,' Fed. R. Evid. 404(b)(1), but rather " 'part and parcel of the charged offense' " *United States v. Williams*, 974 F3d 320, 357 (3d Cir. 2020) (quoting *United States v. Green*, 617 F.3d 233, 245 (3d Cir. 2010)).

The Third Circuit has held that "acts are intrinsic when they prove the charged offense," *Id.* And, although such proof may be extremely prejudicial to the defendant, a court would have no discretion to exclude it because it is proof of the ultimate issue in the case. *See United States v. Gibbs*, 190 F.3d 188, 218 (3d Cir. 1999) (citing Wright & Graham, Federal Practice & Procedure §5239 at 450-51 (1978). In applying the intrinsic evidence exception to Rule 404(b) objections, the Third Circuit has identified two separate categories of evidence termed "intrinsic" – first, uncharged conduct that "directly proves the charged offense", and second, uncharged conduct that was "performed

contemporaneously" and facilitated the charged crime." *Green*, 617 at 245. *Williams*, 974 F.3d at 357. As presented below, and in its initial opposition brief, the practice-wide prescription activity shown in PDMP reporting, insurance claims reports and analysis, pharmacy records, and patient files directly proves essential elements of the charges in the Indictment, occurred within the period charged in the Indictment, and is part and parcel of how Kraynak maintained drug-involved premises and distributed controlled substances outside the usual professional practice. In addition, prior professional licensing actions directly prove Kraynak's knowledge of legitimate medical purposes and usual professional practice, and his subsequent unlawful distribution outside the usual professional practice.

2. Direct evidence of knowledge, intent, legitimate medical purpose, and usual professional practice

In his supplemental brief, Kraynak first emphasizes that the evidence he seeks to exclude is not relevant to prove intent or absence of mistake because he does not assert as a defense that he mistakenly prescribed controlled substances or that he did not intend to prescribe them. Doc. 134, 3. Nevertheless, he contends that he prescribed the controlled substances in good faith for a legitimate medical purpose:

"Dr. Kraynak wrote these prescriptions on purpose specifically to help the individual patients with their medical problems including chronic moderate to severe pain. There was no mistake. These prescriptions were written for a legitimate medical purpose in the ordinary course of treating people and stopping suffering." *Id.* Thus, although he disavows any lack of intent, mistake, or accident, for that matter, in his prescription behavior, Kraynak has made the disputed evidence exquisitely relevant by asserting that he acted in good faith for a legitimate medical purpose and consistent with usual professional practice.

Of course, even absent this profession of purpose, Kraynak's assertion of good faith is directly connected to the requirement under § 841(a)(1) that he knowingly and intentionally prescribed drugs without legitimate medical purpose and outside the usual professional practice.[4] In *United States v. Moore*, 423 U.S. 122 (1975), the lodestar decision addressing the prosecution of physicians under § 841, the Supreme Court concluded that "registered physicians can be prosecuted under §

[4] *See* Doc. 131, 16-19 (reviewing elements of the offenses charged in the Indictment).

841 when their activities fall outside the usual course of professional practice." *Id.* at 124. In *Moore*, the Court quoted and implicitly approved a jury instruction explaining that a physician could be convicted if the jury found that he knowingly distributed controlled drugs "other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.* at 138-39. The Court's language and analysis in *Moore*, including its references to "the usual course of professional practice", "authorized medical practice within accepted limits," and "approved practice," indicate clearly that the applicable standard for determining whether a physician prescribed in the usual course of professional practice was an objective one.[5] *Id.* at 124; 142; 144.

[5] A good faith instruction is not necessarily required where the jury charge contains specific instructions on the elements of knowledge and intent. *See United States v. Li*, 819 Fed.Appx. 111, 118 (3d Cir. 2020). But when given, consistent with *Moore*, the good-faith instructions approved by the courts of appeals have reflected an objective standard for determining whether a physician acted in good faith in prescribing controlled substances. *See, e.g., United States v. Smith*, 573 F.3d 639, 648 (8th Cir. 2009) (we believe that it was not improper to measure the "usual course of professional practice" under § 841(a)(1) and [CFR] § 306.04 with reference to generally recognized and accepted medical practices and not a doctor's self-defined particular practice.; *United*

Moreover, the absence of accident, mistake, or innocent purpose inheres within the requirement under § 841(a)(1) that Kraynak acted knowingly and intentionally in prescribing Schedule II controlled s substances in violation of §841(a)(1). *See* Third Circuit Model Criminal Jury Instruction 6.21.841-4 Controlled Substances-Knowingly or Intentionally Defined (to act intentionally means "to act deliberately and not by mistake"). Consequently, to prove a physician violated

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States v. Merrill, 513 F.3d 1293, 1306 (11th Cir.2008) ("The appropriate focus is not on the subjective intent of the doctor, but rather it rests upon whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." (quotation omitted)); *United States v. Feingold*, 454 F.3d 1001, 1011 n. 3 (9th Cir.2006) ("The term 'professional practice' implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir.1986) (applying *Moore*, 423 U.S. at 139. 335, in dismissing the defendant's argument that "his" requires that the government prove that the doctor prescribed drugs for a purpose contrary to the doctor's own standards of medical practice because "[o]ne person's treatment methods do not alone constitute a medical practice"); *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir.1986) ("To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area."); *see also United States v. Hurwitz*, 459 F.3d 463, 478 (4th Cir. 2006) (collecting cases applying an objective standard of good faith to §841 prosecutions of physicians prescribing outside the usual course of professional practice).

§841(a)(1), "[a]bsent an exemption or qualification, this law would make it a crime for a doctor or nurse in the course of their professional practice to distribute or dispense a controlled substance to a patient unless it were 'done because of mistake, or accident or other innocent reason.'" *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986).(quoting *United States v. Marvin*, 687 F.2d 1221, 1227 (8th Cir.1982), *cert. denied*, 460 U.S. 1081 342 (1983)). Kraynak contends that he prescribed controlled substances for an innocent reason, to alleviate pain, and therefore he has put into contention whether he prescribed drugs for a legitimate medical purpose.

The uncharged prescription activity reflected in the PDMP records, patient files, insurance claims review and reporting, and pharmacy records proves excessive, practice-wide dispensing of Schedule II controlled substances by Kraynak during the period of the indictment, in perilous combinations, and disproves any claim that he prescribed controlled substances in good faith and for legitimate medical purposes, "to help the individual patients with their medical problems including chronic moderate to severe pain." The PDMP reports, like the medical files and pharmacy prescription records for

Kraynak's patients, reflect abnormally high quantities and potentially dangerous combinations of controlled substances, as compared to similar practitioners, that make it more likely than not that Kraynak acted outside the usual course of professional practice in dispensing those drugs. *See Merrill*, 813 F.3d at 1302-1303 (evidence of more than 33,000 prescriptions for controlled substances during multi-year period was directly relevant to prove physician violated §841 by prescribing excessive and inappropriate quantities and combinations of controlled substances and thereby acted "outside the usual course of professional practice"). *See also* Doc. 131, 19-26. Given the drugs' potency and potential for abuse, the amount and combination of Schedule II controlled substances that Kraynak prescribed during the period of medical practice identified in the Indictment is intrinsic to the question of whether he prescribed those substances for a legitimate medical purpose in the usual course of professional practice.

The practice-wide prescription activity, whether compiled in government records like the PDMP or in summaries of prescription claims by insurance entities, or maintained by pharmacies as required by law, represent reliable records of Kraynak's prescribing behavior

during the relevant periods charged in the indictment. They are, after all, a record of his own conduct in issuing the prescriptions for his patients. Given the consistently poor state of Kraynak's patient files, as reflected in Dr. Thomas's report and hearing testimony, practice-wide prescription records from pharmacies, insurance claims, and PDMP reports provide an essential baseline for assessing whether the prescriptions Kraynak issued in individual cases charged in the indictment conformed to objective standards of professional conduct, were for legitimate medical purposes, and fell within the usual course of professional practice. While Kraynak portrays his practice as one of individualized care for each patient based on their unique symptoms and conditions, Doc. 138, 6; 9, his practice-wide prescription behavior during the relevant period of the Indictment shows that he relied upon Schedule II controlled substances as one of his principal treatment modalities, in a manner outside the usual professional practice.

Kraynak also complains that the two professional licensing actions against him are not relevant because there was no finding or admission of wrongdoing. Doc. 138, 2-3. But proving prior wrongdoing is not why those facts are offered. Instead, the administrative licensing

actions prove the essential element of all counts in the Indictment that he prescribed controlled substances with knowledge that they did not have a legitimate medical purpose and fell outside the usual professional practice. When viewed against Kraynak's practice-wide prescription activity, the administrative professional licensing actions, and the professional education courses required as a result of those proceedings, show that Kraynak continued to prescribe excessive amounts of controlled substances, in dangerous combinations, even after two separate administrative licensing actions and two courses of remedial study on controlled substance management and medical record-keeping. *See* Doc. 131, 27-29 (summarizing the period of prescription activity in relation to the administrative actions). The two professional licensing actions are direct evidence of Kraynak's knowledge of what constitutes legitimate medical purpose and the usual course of professional practice. And the records of practice-wide prescription activity show that, in spite of that knowledge, he continued to prescribe excessive amounts and combinations of controlled substances to his patients.

3. Direct Evidence of Maintaining Drug-involved premises.

Counts 18 and 19 charge Kraynak with maintaining drug-involved premises at his medical offices in Shamokin and Mount Carmel from on or about January 2006 and continuing through November 2017, in violation of 21 U.S.C. 856(a)(1). To prove a §856(a)(1) violation, the United States must prove that Kraynak "(1) opened, leased, rented, used, or maintained the premises identified in the indictment, either permanently or temporarily; (2) did so knowingly; and (3) did so for the purpose of illegally distributing the controlled substances identified in the indictment not for legitimate medical purposes in the usual course of professional medical practice and beyond the bounds of medical practice." *United States v. Nasher-Alneam*, 399 F. Supp. 3d 561, 565 (S.D.W. Va. 2019).

Although it is not necessary to prove that illegal drug distribution was the "primary" purpose for which he maintained his medical offices in Shamokin and Mount Carmel, the United States must prove that the illegal distribution of controlled substances was a "significant" one. *United States v. Sadler*, 750 F.3d 585, 592-93 (6th Cir. 2014) (quoting *United States v. Russell*, 595 F.3d 633, 644 (6th Cir. 2010). Like the violations charged in the other counts of the Indictment, the

maintaining drug-involved premises counts require proof that Kraynak maintained those locations for purposes of distributing Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose. *See* Doc. 131, 17; 22-23 (reviewing elements of offenses).

In *United States v. Fuhai Li*, a prosecution of a physician under §§ 841(a)(1) and 856(a)(1), Judge Caputo admitted as intrinsic evidence, practice-wide prescription evidence that included the complete medical record of every patient in practice, PDMP data "for all prescriptions written by [defendant] from January 2011 through January 2015", ARCOS data from area pharmacies between 2011 and 2015, as well as testimony from nineteen former patients, testimony from eight pharmacists "regarding concerns with the frequency and strength of the prescriptions for opioids prescribed" by defendant, and testimony from an expert who had reviewed the files of 60 patients although only 24 patients were named in indictment. M.D.Pa. no. 3:16-CR-0194, 2019 WL 1126093, *2, 9-10; 11 (Mar. 12, 2019). With the exception of wholesale purchases of controlled substances by pharmacies in ARCOS data, the United States essentially plans to introduce the same type of

records and testimony, including testimony by Dr. Thomas, patients, Kraynak's employees, and pharmacists and pharmacy employees who had concerns and complaints about Kraynak's prescribing activities..

As Judge Caputo ruled in *Li*, other district courts have permitted the United States to introduce "overall practice evidence" to prove the significant purpose of a defendant's medical practice to unlawfully distribute controlled substances in violation of §§ 856(a)(1) and 841(a)(1). *See Nasher-Alneam*, 399 F.Supp.3d 561, 567 (S.D.W. Va. 2019) ("evidence regarding the overall scope of defendant's medical practice is relevant to proving the elements of the crime, i.e., whether Dr. Nasher's alleged distribution of controlled substances not for a legitimate medical purpose was a "primary or principal" purpose for his medical practice") (collecting cases); *see also United States v. Singleton*, 19 F.Supp.3d 716, 728 (E.D. Pa. Ky. 2014); *United States v. Sadler*, No. 1:10-CR-098, 2012 WL 3527084, *5 (S.D. Ohio Aug. 15, 2012); *United States v. Evans*, 892 F.3d 692, 696-98 (5th Cir. 2018).[6]

[6] Decisions cited by Kraynak excluding uncharged conduct under Rule 404(b) in prosecutions of physicians for illegally dispensing controlled substances are inapplicable here. In *United States v. Brizuela*, 962 F.3d 784 (4th Cir. 2020), the Fourth Circuit excluded uncharged patient prescriptions dispensed by a physician charged with individual

And notably, the Third Circuit affirmed Judge Caputo's admission of practice-wide evidence consisting of patients, former patients, and pharmacists, not specifically identified and charged in the indictment, as intrinsic evidence, outside the scope of Rule 404(b), to prove the physician "knew he was prescribing pills outside the course of professional practice" and maintained drug involved premises in violation of §856(a). 819 Fed. Appx. 111, 116-117 (3d Cir. 2020). Evidence concerning Kraynak's practice-wide prescription activity during the 11-year period charged in the Indictment, therefore, is admissible as direct, intrinsic evidence of an element central to all the charges in the indictment, that is whether Kraynak's prescriptions for controlled substances were for legitimate medical purposes and/or in

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violations of §841(a)(1), rather than a continuing offense, such as conspiracy, or, as here, maintaining drug-involved premises. But in the codefendant's case, *United States v. Naum*, 832 Fed.Appx. 137, 146 (4th Cir. 2020), the Fourth Circuit affirmed admission of the same uncharged conduct on the count charging conspiracy to illegally distribute controlled substances by the co-defendant, and osteopathic physician. In *United States v. Ignasiak*, 667 F. 3d 1217, the Eleventh Circuit reversed a conviction for illegally dispensing controlled substances based on a Confrontation Clause violation in the admission of five autopsy reports through a prosecution witness, in her capacity as chief medical examiner and records custodian for the office of medical examiner, who did not conduct the autopsies.

the usual course of professional practice.

Accordingly, the evidence that Kraynak opposes – uncharged practice-wide prescription activity reflected in PDMP reporting, insurance claims, pharmacy records, files for living and deceased patients, and testimony of pharmacists, patients, and Kraynak employees – should be admitted as direct evidence to prove that he unlawfully distributed controlled substances and maintained drug-involved premises for the purpose of unlawfully distributing those substances without legitimate medical purpose and outside the course of usual professional practice. After all, those are the ultimate issues in this case, and the evidence Kraynak disputes is directly on point to prove them. *See Gibbs*, 190 F.3d at 218 (discretion to exclude intrinsic is limited because it directly proves ultimate issue in charged counts).

C. The disputed evidence also is admissible under Rule 404(b).

To the extent the contested evidence is not intrinsic or direct proof of essential elements of the charged offenses, the evidence is still admissible under Rule 404(b). All of the disputed items of evidence are relevant to prove Kraynak's knowledge concerning legitimate medical purposes for controlled substances in the usual course of professional

practice and his intent and overall plan to distribute large amounts of controlled substances over an extended period of time. As the Ninth Circuit held in *United States v. Lague*, "uncharged prescriptions of controlled substances in enormous quantities, and in dangerous combinations, support a reasonable inference that the underlying prescriptions were issued outside the usual course of professional practice and without a legitimate medical purpose." 971 F.3d 1032, 1040 (9th Cir. 2020), *cert. denied*, 141 S. Ct. 1695 (2021).

And, as previously argued in opposition to his motion *in limine*, Doc. 131, 28-30, the massive scale of Kraynak's prescription activity reflected in the PDMP and insurance claims records, on both the practice-wide and the individual patient levels, is admissible evidence of Kraynak's plan, design, pattern and scheme to dispense drugs outside the usual course of professional practice under Federal Rule of Evidence 404(b). On this point, the Eleventh Circuit stated in *Merrill*, "To the extent that it can be argued that *each* prescription is uncharged conduct, each is admissible under Rule 404(b) to show evidence of a plan. [emphasis in original]" 523 F.3d at 1303 (citing *United States v. Harrison*, 651 F.2d 353, 355 (5th Cir. 1981). Kraynak's practice-wide

prescription activity is thus relevant to show a plan and pattern of activity that fell outside the usual professional practice.

The evidence of Kraynak's extensive prescription of Schedule II controlled substances also proves his knowledge and understanding of legitimate medical purposes and the usual course of professional practice, his intent to prescribe excessive amounts of controlled substances despite knowledge of those professional standards, and the absence of mistake, accident, or other innocent reason in prescribing excessive and inappropriate quantities and combinations of controlled substances. Uncharged practice-wide prescription information from PDMP reports, prescription benefits claims, and pharmacies are highly probative of Kraynak's unlawful intent to distribute outside usual professional practice and undercuts any claim that the charged prescriptions amounted to "a few bad judgments." *Lague*, 971 F.3d at 1040.

The professional licensing actions are relevant to show that Kraynak continued to dispense large volumes of Schedule II controlled substances even after being professionally disciplined and taking remedial classes. They demonstrate his knowledge of the usual course

of professional practice through professional education courses and the administrative actions, and his practice-wide prescription behavior thereafter demonstrates that he knowingly and intentionally prescribes large volumes and dangerous combinations of controlled substances, despite that training. The timing of the abnormally high volume of prescription activity identified in the practice-wide prescription data in relation to the administrative actions thus is highly relevant to whether Kraynak knew and understood that his practice-wide and individual patient prescription activities were not for legitimate medical purposes and breached the usual professional practice. Doc. 131, 27-29 (reviewing timing of administrative actions and required training and subsequent prescription activity).

Finally, the volume, duration and frequency of Kraynak's prescriptions for controlled substances during the extended period between 2012 and 2016, when he is alleged to have illegally distributed controlled substances, and the 11-year period between 2006 to 2017, when he is alleged to have maintained drug-involved premises, establish plainly that his prescription practices were not the result of accident or mistake and they lay squarely within the charged course of

conduct and relevant time span. The PDMP records report prescription activity from April 2013 to October 2017, Anthem's Express Scripts report summaries prescription claims between January 2012 and November 2014, and the Medicare Medicaid claims summary covers a range from January 2013 through December 2013 – periods of conduct well within the 2012 to 2016 range of the 17 drug distribution counts and the 2006 to 2017 range for the two maintaining drug-involved premises counts.

Kraynak's claims of substantial prejudice arising from the disputed evidence are belied by the fact that the PDMP reports and the Medicare and Blue Cross Blue Shield claims reports, like the records from the pharmacies where his patients filled his prescriptions, compile and summarize the very prescriptions that he admits he wrote. See Doc. 134. (defendant states he wrote prescriptions on purpose). Doc. 138 ("Dr. Kraynak does not deny writing any of the prescriptions that he wrote."). The origin and source of the practice-wide prescription information that he disputes is Kraynak himself. He issued the prescriptions for specific drugs, for specific patients, and on specific dates with the purpose that his patients have them filled at pharmacies

and with the understanding that, if coverage applied, that their insurers would pay for some or all of the cost of the drugs. Kraynak's complaints about the accuracy of the PDMP reporting, pharmacy records, and insurance prescription claims summaries really go to the weight of the evidence rather than admissibility under Rule 404(b). He is certainly free to use similar prescription information and prepare his own reports and summaries for presentation at trial.

Kraynak's objections on prejudice grounds to references in various reports to terms such as prescription "cocktails" and "pill mill" are of little merit. As the Anthem Blue Cross summary makes clear the term "cocktail" refers to known combinations of prescription drugs that increase the effects of those drugs and potential risks to the patients. Indeed, the United States intends to present the testimony of pharmacists from multiple pharmacies who observed that many of the prescriptions issued by Kraynak for his patients included "cocktails" or combinations of oxycodone, carisoprodol, and benzodiazepine. Likewise, Kraynak has failed to show how the term, "pill mill" will prejudice him. Courts have denied motions *in limine* and admitted evidence and argument using these types of terms or phrases at trial.

See, e.g., United States v. Gowder, No. 19-5894, 2020 WL 7863139, at *3, (6th Cir. Dec. 30, 2020) ("a doctor issuing excessive prescriptions with little information about each patient permitted the jury to infer that the doctor knew he was part of a pill mill"); *United States v. Guzman*, 571 F. App'x 356, 361 (6th Cir. 2014) ("[Defendant] likewise provides no authority for [his] argument that the phrase 'pill mill' is unduly deprecatory . . . To the contrary, it is a term commonly used by the courts including, our court, to describe illicit pain management clinics."); *United States v. Fuhai Li*, No. 3:16-CR-0194, 2019 WL 1126093, at *9 (M.D. Pa. Mar. 12, 2019) ("According to the Government, this evidence established beyond a reasonable doubt that Dr. Li operated his pain management practice as nothing more than a 'pill mill.'").

Kraynak has not shown that the prejudice from the evidence he seeks to exclude substantially outweighs the probative value of the practice-wide prescription activity and the professional licensing actions under Federal Rule of evidence 403. The probative value of the PDMP reports, the insurance claims summaries, the prior professional licensing proceedings, and prescription benefits and claims summaries,

pharmacy records, and the combinations of controlled substances heavily outweighs any risk of unfair prejudice, confusion of issues, misleading the jury, or needlessly presenting cumulative evidence.

As argued in the government's initial opposition brief, the disputed evidence will be presented through summaries and charts, rather than through the voluminous data of Kraynak's many thousands of prescriptions for Schedule II controlled substances. The evidence will be presented with a focus on the medical purpose of the prescriptions, whether they were within usual professional practice, and Kraynak's plan, design, knowledge, and intent in dispensing the drugs. Any potential risk of prejudice will be minimized through the Court's instructions on the elements related to the defendant's knowledge and intent, medical purpose, and usual professional practice and by any additional limiting instructions on the jury's consideration of the evidence. *See, e.g., United States v. Zielke*, 2021 WL 1163868*6-*7; *United States v. Werther*, 2013 WL 5309451 at *9 (E.D.Pa. Sept. 23, 2013). Based on the substantial probative value of the disputed evidence, and the effective mitigation of any risk of prejudice through limiting instructions, the practice-wide prescription activity and the

prior professional licensing actions should be admitted at trial.

III. CONCLUSION

For the additional reasons stated herein, and those previously presented in its initial opposition brief, the United States respectfully requests that the defendant's motion *in limine* be denied.

Respectfully submitted,

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Dated: July 6, 2021

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	NO. 4:17-CR-00403
	)	
v.	)	
	)	(JUDGE BRANN)
	)	
RAYMOND KRAYNAK,	)	
Defendant	)	(ELECTRONICALLY FILED)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the Office of the United States Attorney for the Middle District of Pennsylvania and is a person of such age and discretion to be competent to serve papers.

That this 6th day of July 2021, she served a copy of the attached

GOVERNMENT'S BRIEF IN OPPOSITION TO KRAYNAK'S SUPPLEMENTAL BRIEF IN SUPPORT OF HIS MOTION *IN LIMINE*

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